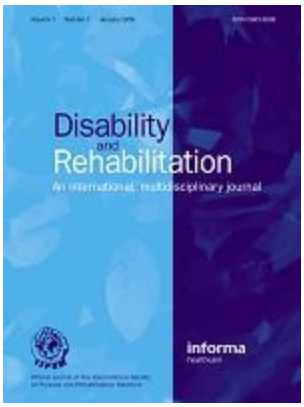

Feasibility of a randomised controlled trial to evaluate home-based virtual reality therapy in children with Cerebral Palsy

Journal:	*Disability and Rehabilitation*
Manuscript ID	TIDS-09-2018-097.R2
Manuscript Type:	Research Paper
Keywords:	Cerebral Palsy, child, Physical therapy modalities, Randomised Controlled Trial, Computer Assisted, Therapy

Implications for Rehabilitation

- Home-based interactive computer gaming was feasible, safe and cost effective as a therapy adjunct.
- Discontinue if additional pressures are present: imminent surgery, family resilience to technical difficulties, negative system feedback, after-school activities
- Change in Gross Motor Function Measurement scores varied by severity of Cerebral Palsy

Feasibility of a randomised controlled trial to evaluate home-based virtual reality therapy in children with Cerebral Palsy

Abstract

Purpose: Evidence is increasing for effective virtual reality therapy for motor rehabilitation for children with Cerebral Palsy. We assessed the feasibility of a virtual reality therapy mode of intervention, appropriateness of measures, and potential cost-effectiveness.

Methods: A 12-week, 2-group, parallel-feasibility trial (ISRCT 17624388) using Nintendo Wii Fit™ at home. Children aged 5–16, with ambulatory Cerebral Palsy, who were able to follow simple instructions were randomised to two groups; one supported by physiotherapists (individualised activity programme), the other unsupported with children having free choice (control). Children were assessed in clinic at baseline, week 6, and week 12 by blinded assessors. Feasibility of the intervention was assessed via recruitment, adherence, and usefulness of measurement tools.

Results: Forty-four children were eligible (out of 48 approached): 31 consented, 30 were randomised, 21 completed the study; 10 in the supported group and 11 in the unsupported group. Nine children discontinued from tiredness, after-school activities, homework, surgery, technical difficulties or negative system feedback. The supported group completed 19 of 36 (IQR 5-35) possible sessions; the unsupported group 24 of 36 sessions (IQR 8-36). Gross Motor Function Measure scores varied by Cerebral Palsy severity after the intervention. There were no adverse events.

Conclusion: Virtual reality therapy offers potential as a therapeutic adjunct for children with Cerebral Palsy, warranting substantive confirmatory study. Gross Motor Function Measure, with modifications to improve sensitivity, appeared appropriate as a primary measure, with Timed up and Go test secondary. The intervention was inexpensive costing £20 per child. An explanatory trial to evaluate the clinical/cost-effectiveness of commercial system virtual reality therapy is feasible with minor methodological adaptation.

Keywords: Child; Cerebral Palsy; Randomised Controlled Trial; Physical therapy modalities; Therapy, Computer Assisted; Exercise Therapy

Introduction

Cerebral Palsy (CP) is an umbrella term for a collection of disorders that occur as a result of primary non-progressive damage to the developing foetal or infant brain, occurring at a rate of approximately 2 per 1000 live births in the UK or 254,000 live births per annum, globally [1]. The impairment of the developing brain affects muscle tone and strength, which limits movement and physical activity. Co-morbidity [2] can cause further disturbances of sensation, perception, cognition, communication and behaviour, with conditions such as autism, epilepsy, and secondary musculoskeletal problems [3].

In the UK, children with CP experience a decline in the amount of therapy time they receive as they age, from 12 hours per year for 0 - 6 year olds, to seven hours for 12 - 18 year olds [4]. Further, a reduction in therapeutic exercise is exacerbated by general resistance to home-based physical activity [4-6]. Children with more severe and complex impairments receive the most therapeutic input, leaving ambulatory and older children with CP to receive as little as two hours of therapy per year [5, 6].

New approaches are needed to counteract this poor access to therapy. To be practicable, new home and school-based interventions need to be low-cost, easily deployable, flexible and acceptable. Whilst motor learning theory supports intensive task focused therapies for CP, poor motivation has been observed in current therapies with insufficient applicability to daily function [7-11]. Therapeutic modes need to be both motivating and responsive to the needs of families and be developed with direct input from families of children with CP to ensure greater alignment and applicability to daily function. Home-based therapies delivered by parents are showing some promise as well as challenges for some families [12, 13]. Virtual reality therapy (VR therapy)

carried out in the home may be one potential avenue for increasing children's engagement with therapy and improving outcomes.

Virtual Reality Therapy

As digital technology becomes more prevalent and pervasive for the current millennial generation(s) of 'digital natives' [14], there has been a parallel and unprecedented growth in assistive and rehabilitation digital technology for children with additional needs [15]. However, practical frameworks that align technology to clinical need remain elusive [15]. In particular; pragmatic questions remain regarding issues of acceptability, feasibility, and patient data security for physical activity with smartphones, global positioning systems, and use of large-scale patient data sets [16]. Scrutiny is required to ensure digital healthcare services are provided that are appropriately evidence-based, cost-effective, and fit for purpose. Voices of dissent even suggest in the title of journal articles that digital technology may be more 'hype than hope' [17].

One avenue for digitized patient care is in the use of Virtual Reality (VR) therapy that uses motion capture digital technology to assist as part of a therapeutic treatment programme [18, 19]. A recent study by this research team identified the potential of VR therapy in the home as supportive to active therapy intervention, and is welcomed by children and families but a clearer understanding of the potential impact is needed [20]. Commercial systems such as the Nintendo Wii Fit™, Xbox Kinect™, or bespoke systems such as Mitii™ have all been tested to date with varying success in stroke rehabilitation, dementia, children with developmental coordination disorder, acquired brain injury and CP [21-23]. Recent results suggest that therapy with the Wii Fit in-clinic may be more effective than standard physiotherapy intervention [24]. However, published studies are often beset with problems of inadequate sample size

[25, 26], non-standardisation of measurement tools [27], lack of adherence, unclear dosage within programmes of therapy, lack of clarity for the role of the therapist, and alignment of aims with daily life skills [28]. For example, James et al. [23] demonstrate the 'Move it to improve it' (Mitii™) VR system is partially effective for improving activities of daily living in children with unilateral CP over a 20 week period, but problems were still experienced in sustaining the novelty of the intervention after the first 20 hours of therapy.

One in four children is reported to have a video game console such as the Nintendo Wii or Sony PlayStation [17], or more recently the Xbox Kinect in the home. A recently published survey in England suggests this number may be far higher, with 97% of families in possession of a commercial games console, with active gaming consoles such as the Xbox Kinect making up 68% of total ownership [20]. Families of children with CP reported that 28 of 61 (48%) survey respondents already used or had attempted to use the Wii Fit™ for therapeutic purposes [20]. This raises the possibility of an additional motivating tool in the home which may be supported by physiotherapy directed activities, and enhance patient adherence for home-based exercise regimes.

The prohibitively high costs of bespoke VR systems for physiotherapy interventions takes access to such technologies beyond the reach of most patients and services [23]. To address this issue our focus is on identifying affordable options, with the most likely candidate technology being modified entertainment and exercise systems that are commercially available. There is "great opportunity to use interactive technology as a holistic intervention to address broad ranges of impairments" [p15, 29]. Health inequality could also be reduced by allowing individuals to carry out the intervention at home, with their family, and at a time of their choosing [28], alongside personal goal setting, which is paramount in rehabilitation practice [28, 30]. As the gap

between research and practice is narrowing, work is more gradually focusing on the integration of VR and serious games into therapy according to three key elements; prevention, participation and neural plasticity [31]. Our work here focuses on assessing the feasibility of using low-cost VR therapy in the home.

Before embarking on a definitive trial, we have undertaken a feasibility study to see if VR therapy, using commercially available systems, may be one avenue to increasing therapeutic engagement with children with CP.

Study Aims

The primary aim was to explore the feasibility of a future multicentre randomised controlled trial (RCT), testing the clinical effectiveness of our chosen methods and measures, and the cost effectiveness of a commercially available console for virtual reality therapy in children with ambulatory CP. Therefore we sought to investigate:

- Whether procedures for recruitment attracted sufficient participants
- If children adhered to the recommended programme and
- Whether proposed measurement tools, methods of analysis, and resource implications/costs were appropriate in relation to outcomes

We aimed to estimate the precision of group differences for our five main outcome measures, to begin to gain greater clarity of the sensitivity of these measures to detect relevant change for the potential utility of these measures in a definitive RCT.

Additionally, we investigated cost-effectiveness of whether the treatment can be offered through physiotherapy services in the UK National Health Service (NHS), if there is fidelity to the delivery of the treatment, what outcomes are important to

measure, and the profile of children for whom the treatment may be effective and ineffective.

Method

The study procedures were approved by the Lancaster National Research Ethics Committee (NW1499), International Standard RCT number 17624388.

Recruitment and Consent

Children with CP were identified from Community NHS Trust Child Development Teams in South-East England (see Figure 1, process of informed consent). Families were provided with information about the study by their regular clinician during appointments or by mail. The opportunity to take part in the trial was advertised through posters, or flyers distributed to clinicians at local study days, study presentations to Child Development Teams or through local clinical research networks. Participants were also able to self-refer to the research team who checked suitability with the child's care team. After participants registered their interest in the study to their clinical team or through self-referral there was a 24-hour cooling off period. Participants were then approached by a research assistant to book an appointment to check eligibility and obtain written consent. A record of participation interest and consent was made on clinical notes so as not to duplicate contact with families, and of families not wanting to take part, to determine the likely size of population needed to run a definitive RCT (Figure 2). Recruitment took place between 27/7/2015 and 10/5/2016 and follow-up ended on 2/8/2016. Based on local population size and prevalence predictions we anticipated that by recruiting children of school age (i.e. 5 to 16 years) we would be able to reach a target of 30 children, assuming a 40% positive response rate. Julious [32] recommends that a pilot trial should have at least 12 participants per group for the

analysis, therefore allowing a drop out of 20% post randomization.

Insert figure 1 here

Inclusion criteria

Ambulatory children aged 5 to 16 years with bilateral or unilateral CP were invited to take part in the study. Children were included and classified using Gross Motor Function Classification System (GMFCS) levels I and II [33]. At GMFCS I and II children are able to walk independently over short distances without the use of walking aids. Children had to be able to follow task instructions.

Exclusion criteria

Children with epilepsy who were photosensitive or had had a seizure within the previous year or were taking anticonvulsant medication were excluded.

Randomisation

Participants were randomised with Minimpy [34] using minimisation [35]. This gives a 70% probability of a group allocation which minimises imbalance on variables that could influence the outcome, namely gender, type of CP (unilateral or bilateral), and age group (primary school age (under 11 years) or secondary school age (over 11 years). Table 2 shows the balance of minimisation.

Randomised Groups

Children were allocated to either a physiotherapist supported group with prescribed games (SG) or an unsupported group with freedom over game choice, the control group (USG). The SG was given a structured home-therapy programme. The USG had free use of their console in order to control for the Hawthorne effect [36] and further, it was

considered unethical to withdraw families' own consoles for the 12-weeks of the study.

Measurement tools

Study Outcome measures

Five measurement tools were employed, and considered for their measurement properties, suitability for detecting change, and potential to support the estimation of a sample size of a future RCT. Clinical measurement were taken by a physiotherapist blind to allocation at baseline, 6 weeks, and 12 weeks.

The **Gross Motor Function Measure-66** (GMFM-66) is a clinical measure designed to evaluate change in gross motor function in children with CP. This could potentially be a primary measure in future studies as it is already the *de facto* gold standard [e.g. see 37 for details] for measuring impact on motor function for children with CP.

There are five dimensions to assessment; lying and rolling, sitting, crawling and kneeling, standing, and walking, running and jumping [37]. This tool has a strong track record of use in studies with children with CP and VRT [31, 38-39]. Although GMFM-66 is considered to be better clinically than the longer GMFM-88, it has been shown to report changes more slowly postoperatively in gross motor function compared to GMFM-88 [40-41]. For work with assisted technologies, GMFM-66 is considered to be a sensitive tool capable of detecting gross motor improvement in children with CP [33].

The Timed up and Go test (TUG) measures mobility, and active and static balance. It involves recording the time taken to get up from a chair, walk three metres, walk back to the chair and then sit down. It is conducted using the normal mobility aids an individual may need. This tool has a track record of use in studies with children with

CP and VRT [33, 42-43] and has high detection rates for functional mobility [44]. The test has high reliability within session (intra class correlation of 0.99) and test re-test of the same level [45]. Whereas the GMFM measures gross motor skills, the TUG has been found to show accompanying changes in movement speed [46].

Bruininks-Oseretsky test of motor proficiency-2nd Edition – short form, Balance subscale, and Running, Speed and Agility subscale (BOT2) [47]. This tool was included because of its effective sensitivity to change in motor proficiency conducted during our own pilot study with children with developmental coordination disorder [21]. We also wished to consider whether VRT had any impact on aspects of upper-limb function [48-49]. Additionally we are unsure of ceiling effects of the GMFM-66, which this feasibility RCT study assessed.

Goal Attainment Scale (GAS) scores patient's individual goals, is particularly sensitive to change, and encourages patient intervention [50]. This tool has been used in studies with children with CP and VRT, and has been included because of its effective prior use in establishing and maintaining interest in patient intervention [30].

Three of the four tools have been used in previous studies of VRT in children with CP (GMFM, TUG, GAS) whilst BOT-2 scores are untested with VRT and CP. The present feasibility study investigated how appropriate these measurements would be for gathering data from which effectiveness could be assessed. We also assess what the primary outcome measure might be, and how the four measurement tools work together, if at all, if they potentially cause fatigue and/or pain, and whether they are useful clinically for showing changes in functional balance and secondary effects following VRT in children with CP.

Psychosocial outcomes were measured through recorded diaries (see supplementary material S1) of the child and parental experience of using VRT. The **Strengths and Difficulties Questionnaire (SDQ)** which reflects, in this instance, parent report of social and emotional behaviour was also administered at the start and end of the study to assess potential broader impacts [51].

The Edinburgh handedness inventory [52-53] is a short four item questionnaire asking whether a child uses one hand predominantly for certain tasks such as writing, throwing, using a toothbrush ('always', 'usually', 'both equally') and produces a laterality quotient of either left, right or mixed handed. This measurement was used as children and parents were often unsure which hand was predominant if the child had bilateral CP.

Diaries of games undertaken were utilised to provide information of subjective ratings of acceptability and enjoyment. Participants also took part in a postal questionnaire on physical activity and participation in daily tasks.

Public and Patient Involvement (PPI)

Reporting of patient and public involvement in this trial uses the GRIPP2 (table 1) reporting checklist [54].

Table 1 about here

Two parallel streams of public and patient involvement in Sussex and Devon informed the research. Parents in both groups agreed that getting children to do regular therapy exercises is a struggle. Parents perceived that using Wii Fit™ active computer games would be popular with children and families, and improve adherence to therapy programmes. Initial work on this project involved testing out not only the Nintendo Wii

Fit™, but also the use of Microsoft Kinect technology. We held a parent consultation day in Sussex and our two co-applicants/authors emerged from this and expressed interest in taking part in the study.

Aim of Public and Patient Involvement in the study

Parents were an integral part of the research project supporting consulting of drafts of documents to be used during the project including information sheets and consent forms. Parent advice ensured these were informative and accessible. All materials were written, and appropriately modified with parent advisors and the Peninsula Cerebra Research Unit (PenCRU) Family Faculty.

Methods used for Public and Patient Involvement in the study

Two parent carer co-applicants of the research project became consultant parent advisers to the steering committee. There was also support from a parent carers' working group in the PenCRU Family Faculty at the University of Exeter Medical School. Trial steering committees were held in person or in teleconference every four months. Monthly updates of recruitment and study news were sent to all involved in the study. Four further consultant parent meetings were held over the course of the study to test run trial method, design of the project logo review documentation, and review the whole project and discuss next steps after data collection was complete. PenCRU was consulted during initiation of the trial, and on completion of the trial with results.

Procedures

Data Collection

Data were collected by five senior physiotherapists over a period of 13 months at four

NHS child development centres across one county in South-East England. All data were collected utilising clinical rooms. The size of each room, repeat availability for follow-up, and variety of equipment in each clinic varied across centres.

Schedule for Follow-up

Both groups were given a Nintendo Wii Fit™ package and asked to play certain games (see supplementary material S2 for programme) for 30 minutes, 3 times per week for 12 weeks, and asked to keep a diary of their activity.

Children in the SG were supported by a physiotherapist (not the physiotherapist who carried out measurements) who contacted the parents of the child every two weeks by telephone to assign games, and subsequently checked how the prescribed programme of activity was progressing and suggested scaffolding for extension of games and activities for motor progress, as necessary. In the USG fortnightly phone contact (see script in supplementary material S3) was offered for general queries e.g. was the system working? However, no specific advice on games and activity scaling was provided. A record of the number of calls, duration, voice messages and summary of conversations was made. No repeat phone calls were made when there was no answer.

Analyses

Continuous variables were summarised using means and standard deviations, medians and interquartile ranges, and categorical and binary variables using frequencies and percentages. Normality of outcomes was not assumed so differences in outcomes measures between the groups are presented with bootstrapped bias corrected and accelerated 95% confidence intervals. All analysis was done using Stata software, version 14.2 [55]. Recorded clinical measurements were quantitative. Data captured using health economic reports, and participant diaries produced both qualitative and

quantitative data. Inferential significance was minimally considered due to the exploratory, feasibility nature of this study. Thus 95% confidence intervals were stated for between-group comparisons and discussion limited in this respect to avoid misinterpretation.

Health Economics

A health economics analysis at the individual patient level, and taking the NHS perspective, was conducted alongside the clinical study. The health economics analysis investigated the proportion of therapists that completed and returned logs, the number of calls made and completeness of the calling records (relative to the maximum of 6 calls over the 12 week period), and the amount of therapist time shown as supporting children in the study. Mean amount of time spent by therapists during phone calls to the intervention group was calculated. The cost per child was estimated using validated national unit costs in the UK [56], applied to recorded therapist time input. Data appertaining to the USG were examined but costs were not calculated since this was the control condition and researcher contact was for the purposes of maintaining contact with participants in the trial, and not to provide therapeutic input.

Results

Feasibility RCT

Randomisation and Consent

Figure 2 shows the CONSORT diagram of enrolment to analysis throughout the trial. Randomisation through minimisation was successful (see table 2). Minimisation achieved a balance between both groups, with only marginal imbalance between female versus male participants (20 and 33% respectively). Three quarters of participants in

USG used a study-provided console (75%), compared to just over half (57%) in the SG (see tables 3 and 4, and supplementary table S1 for intervention strategy).

Insert figure 2 and table 2 here

Recruitment and drop out

More children were at GMFCS 2 (66%) than 1 (33%). Forty-four children were assessed for eligibility. 14 were excluded as they were outside the acceptable age range, 1 child with GMFCS III was mistakenly approached by a clinical team. This child was offered a Wii Fit™ to take home and try, as they were upset when they realised they did not meet inclusion criteria. This child was not included in the trial. Five children declined to participate, 4 gave no further response on approach, and 1 was recruited/consented but not randomised due to a clinical decision that an upcoming operation placed the child outside the inclusion criteria, and that the study would be a complicating factor in post-operative recovery. Thirty individuals (68% of those approached) met the inclusion criteria and consented. It is not known how many throughout the region may have seen adverts and flyers for the trial out of a total GMFCS I-V estimated population of 300, of which approximately 61% or 183 would be children with CP in GMFCS I/II [57].

Ten of the children in the SG (67%) and 11 in the USG (73%) completed the trial. There were a variety of reasons for participant dropout, showing that this population group lead complex lives and are susceptible to a range of problems. Children who completed the study experienced tiredness (3 children) as a factor causing dropout, which also caused reported 'time off' from using the Wii Fit™ during the trial. School was also a factor causing dropout reflected through children's after-school activities (1 child), and homework (1 child) where some children found the burden of the study too much. Additionally, where surgery (1 child), or difficulties with using the

technology e.g. where the balance board could not 'read' the child was standing on it (1 child). This was because for children with unilateral CP the balance board was frustrating as it was not reactive enough to detect variation in weight bearing between left and right side. This is limiting where children have unilateral CP as the balance board requires an equal split in weight to correctly detect activity. Two children also reported "no time" to carry out the activities. Lastly, one child with a comorbidity of autism could not adhere to the measurements and so left the study.

Willingness of clinicians and to recruit participants

PTs recruited most participants. Occupational therapists and Consultant Paediatricians also helped to recruit. Trial physiotherapists worked on a casual basis which meant that team members did not have sufficient "buy-in" to the project and worked as and when they saw fit. Research team members became responsible for arranging appointments which did not work effectively alongside clinical caseload pressure which took precedence.

Physiotherapists carrying out measurements

All therapists received a one day training package, but it was not possible – even with the utilisation of a senior PT as part of the research team – to verify the level and quality of professional other than National Health Service pay banding. Variation in levels of experience, and across sites, was noted.

Insert table 3 and 4 here

Adherence to Programme

The SG (see table 5) completed a mean number of 19/36 sessions (56% adherence) whilst the USG completed 24/36 (66%). There were no adverse events. Children at

GMFCS level II completed more sessions than GMFCS I (27 v 20), with higher mean subjective enjoyment rating of 3.1 v 2.1/5 (see table 6). Total number of minutes varied considerably across both groups, and whilst the USG spent more time using the Wii Fit™ (mean 1230 minutes, S.D. 1003) compared to SG (mean 819 minutes, S.D. 634). Overall adherence was high; mean total minutes spent for SG was 75% of what was suggested (mean 819 minutes, compared to recommended 1080) whereas the USG group carried out 96% of suggested activity time. For two cases in the unsupported group the number of sessions was unreported, but total minutes were extracted from the Wii Fit™ memory.

Feasibility of Study Measures

Overall, the measurement tools seem appropriate to VR therapy (see tables 7-9). The GMFM-66 was responsive to use but may have a ceiling effect as some children were high scoring throughout the study. Children at GMFCS II saw the most change in GMFM-66 score between baseline and week 12 in the SG, from 67.8 to 75 points (where the maximum is 100) on the scale whilst doing less activity overall than USG. Change in SG group was, on average, 6.2 points (75.2 to 81.7) whilst USG group experienced a change of 3.4 points, from 81.4 to 84.8, but began from a higher average baseline score.

The Timed up and Go test (table 7) showed equivalent score change across both groups. In seconds the SG group got quicker (6.2 to 5.5 seconds) as well as the USG group (6.6 to 5.7). The USG showed marginally more improvement. The test was easy to administer, although PTs did find that there was often variation between the style and height of equipment e.g. chairs or size of available rooms at CDCs.

The BOT2 short form SG score increased from a mean of 46.5 to 52.3, compared to USG of 45.8 to 47.7 where the maximum raw score is 88. This is a similar change to GMFM results. For the balance subscale the difference in means was SG 19.9 to 24.1 and USG 22.4 to 25.1, a change in mean score of 4.2 (SG) and 2.7 (USG). BOT2 was found to be problematic in taking too much time to record all scores.

The GAS showed greatest improvement of all recorded scores, as scores in SG showed substantial improvement of targeted outcomes from 35.2 to 54.9 (increase of 19.7), with two out of three individualised targets successfully achieved. USG achieved similar results, with an increase in score from 37.6 to 58.8 (21.2).

The Strengths and Difficulties Questionnaire (SDQ) was easy to administer with the parent often filling in the 16 point questions whilst other measurements were taking place. Change in children's strengths and difficulties were observed e.g. social interaction for example in SG 12.5 to 10.9, and USG 12.6 to 9.4 (with a reduction indicating positive change). The parent-completed SDQ showed both SG and USG groups to be within the "close to average" category with symptoms marginally improving.

Insert table 5 and 6 here
Insert table 7 and 8 here

For a future RCT, measurement tools will need to be significantly streamlined to include those measures that best detect change in motor function for children with CP and are easy to use without causing significant burden e.g. stress or anxiety to the child, family or therapist, and are acceptable to parents and children.

Insert table 9 here

Feasibility of Technology

The main issue with the use of a commercial console was in the presence of consoles already in many homes. However, 75% of participants used a project console (table 4), enabling data retrieval through the SanDisk (SD) card. 25% of participants elected to use a family owned console, which meant that data could not be collected through SD cards. SD data on the Wii Fit™ is unreliable: it is unclear which user is active even when participants were given a pamphlet and talked through the creation of personal user profiles. The Wii Fit™ cannot isolate the difference between users except in querying weight change, but where children are close in weight (as happened with a family with twins) it is impossible to determine who was using the console from Wii data. Other children were also so light, due to age, and possibly lack of bone mineral density due to impaired weight-bearing, that the balance board could not detect that they were on the board, highlighting limitations in the technology. Without the purchase of SD cards being sent home, potentially invading home gaming privacy, this was lost data for those who did not use a project console.

End of Project Survey

40% of comments in the supported group were positive toward the programme. Activities were perceived as generally getting easier over time which was seen as strength of the intervention across both groups. There was variation in attitude toward difficulty of the games and in achieving better game scores; some children were frustrated, whereas others enjoyed the challenge. This was equal across both groups. Families found the equipment set-up amenable, but the balance board was unable to detect weight of younger children (e.g. 5 year olds) especially those with hemiplegia.

Study results of PPI in the study, including both positive and negative outcomes

Parents enabled drafts of documents to be clear and easily accessible with few errors in interpretation of documentation. The only error with study documentation was with the study diary (supplementary table S2) which was perceived to imply "Monday, Wednesday Friday" as days when study activity was expected to be conducted. High recruitment and adherence to the study program is likely to have occurred due to the input of PenCRU and parent consultants.

Health Economics

The children were monitored during the study by three therapists. Two therapists supported children in the intervention group (one supported nine children, the other four). The third therapist supervised all 15 children in the unsupported group. Logs were returned for 28 children, 13 (87%) in the supported group, 15 (100%) in the unsupported group.

Therapists' logs for the supported group (SG) showed a total of 54 calls (i.e. 4.2 per family) were made (69% of the maximum of 78). Of these 29 (54%) involved a conversation with a parent. The remainder of calls were not answered or went to voice mail, or in two cases parents stated they were too busy to speak. The mean time spent on phone calls, including those with no response, (see supplementary table S3 for phone call questions) was 35 minutes, ranging from 5 to 55 minutes.

For the unsupported group (USG), research fellows reported 74 calls (82.2% of the expected 90), 4.9 per family. Of these 40 (54.1%) were answered. The mean duration of calls per child was 12.6 minutes, ranging from 2 to 20 minutes. In addition, the researcher sought advice from the supervising physiotherapist for three children

whose parents raised particular issues about the use of the Wii. Total therapist time on these three enquiries was 45 minutes (5, 10 and 30 minutes respectively).

The cost of a therapist's time over the 12 week intervention was £20.10 per child in the supported group (A). This is based on an hourly rate for a band 5 physiotherapist (AfC specialist level) of £37 [56]. The physiotherapists in the study, however, were band 7 (advanced / team leader) and 8 (principal / consultant). Costs at these higher levels would be around £30 or £40 per child respectively.

Discussion

Our primary aim was to determine the feasibility of a future multicentre RCT by testing the clinical effectiveness of methods and measures, and cost effectiveness of a commercially available console for VR therapy for children with ambulatory CP in the home. PPI had a significant impact on study direction (home versus clinical use), acceptability and preparedness of study documentation, and acceptability of study set-up (games, set-up of technology, programme of games). It is possible that even more contact with PPI members would have led to more insight, however it is important not to burden families and carefully foster of PPI relationships. In a future RCT we would aim to enable more pro-active and unprompted PPI to occur.

Recruitment procedures attracted sufficient participants, children adhered to the recommended programme, measurement tools and methods of analysis were appropriate, with some exceptions, and resource implications/costs in relation to outcomes found that the staff cost was low. However, the protocol may not have been completely acceptable to physiotherapists as therapists' logs for the supported group showed only 54% of phone calls resulted in a conversation with a parent. Physiotherapists were responsible for arranging phone calls to families and so it is

possible that they did not occur at convenient times for the parent. If arrangements in a future trial were made to phone only at certain times, this could increase the proportion of calls that resulted in parent contact.

We calculated group differences with 95% confidence intervals for our five main outcome measures, but the predictive validity of these requires data from future studies to gain greater clarity of the sensitivity to detect appropriate change as well as the potential utility of these measures in a definitive RCT.

This study found that the treatment could be offered through physiotherapy services in the NHS. The treatment delivery i.e. in the home had fair fidelity in participants conforming to recommendations of the physiotherapists, and also potentially in the frequency and duration of sessions undertaken across both groups (USG and SG). There is some evidence that the novelty of the games wore off at about the 7th week with a tapering off of usage. A future RCT may require participants to use a project console to ensure complete data capture.

'Active Ingredients'

One of the biggest issues surrounding the use of digital therapeutic intervention is the identification of 'active ingredients' necessary for VR therapy to be useful to sustain impact. Our findings are supported by Levac et al [58] who found that active gaming home-use groups showed significant improvement in GMFM scores, compared to clinic-based programmes. Deutsch et al [31] suggest that active video gaming (AVG) research should be primarily aimed at prevention, participation and plasticity; our study focusses on understanding low-cost therapeutic participation in the home. Levac et al [19] suggests that therapists should focus on gaining sustained engagement over time with the whole family if therapy is to be carried out in the home. Children and families

should be given the opportunity to engage with their own therapy, have autonomy over choices about activities, and be able to problem solve difficulties [19, 28]. Intrinsic and extrinsic motivational factors need to be emphasised so that adherence is high, and therapies are more likely to be successful. Levac [28] suggests therapists should develop their role carefully as a facilitator of the technology, by selecting optimal games, monitoring progress -as attempted here with phone calls- with the assurance that there is clear alignment between daily activities and motor outcomes that are important to the patient. For example, one child who was part of this feasibility study had a severe visual impairment, had extremely motivated parents and therapists were willing and motivated to make the study accessible for the child. An additional hour was spent by a senior physiotherapist on the project, acquiring a K-walker for use for the 12 weeks of the study. The participant subsequently experienced a high change in GMFM score across the 12 weeks. Children experienced a waning of their interest in the 7th week, so sustaining interest continues to be problematic. However, the deployment of therapists using focused and personalised scales in clinical conversations such as in the use of GAS, making phone calls to individuals in lieu of clinical meetings, and asking participants to keep diaries may help adherence to protocols.

Van Hedel and Aurich [15] go further than Levac and state that rehabilitation technology should only be used with responsive patient groups, in which case the identification of patient 'responsiveness' to VR therapy becomes vitally important. If motivation is related to adherence, which in turn is related to responsiveness then exploring 'desires', interests, and enjoyment as part of participation makes VR therapy/AVG as much about psychological attitudes surrounding the technology as well as actual improvements in motor function. This is reflected in the USG arm of our study in which participants were free to use the games as they wished; some of whom

maintained interest and persisted with the use of the VR therapy throughout the 12 weeks with the median total minutes spent playing games was higher than the SG. A further issue to consider is the transfer of gains made in a 'virtual world' to real-world actions. Recent research has suggested that upper limb reaching actions may differ in virtual environments physical environments, emphasising the need for accurate spatial and temporal resolution of avatars with haptic interfacing to facilitate transfer of gains made to real-world tasks [64]. The use of the balance board with the Wii Fit™ may facilitate better transfer of gross balance gains to the physical world with the enhanced sensory feedback provided. Further investigation is required to identify appropriate interfacing devices for individual children that mirror real world movements.

Levac points to therapists who measure client motivation in a standardised way that can be replicated e.g. Tala et al's (2015) Paediatric Motivation Scale (PMOT) or the O'Brien and Thomas (2010) User Engagement Scale, which measures novelty and so captures the potential dropout of participants due to waning interest from technological innovation. Engaged learners are more likely to have improved outcomes, such as memory consolidation [28]. Thus, while VR therapy has potential for home-based use to augment therapy programmes, there is a need to consider factors influencing uptake and adherence to home-based applications.

Appropriateness of measures

Motor function was acceptably measured by GMFM-66 as children cooperated with its use, and there appeared to be no floor and ceiling effects. Measurement tools seemed appropriate to use alongside VR therapy. Timed Up and Go captured change, but with only marginal a difference between the two groups, which may reflect progress in functional mobility in both groups associated with the frequency (dose and duration)

of use of active video games, with or without therapy support. The BOT2 running speed and agility tool was inappropriate for widespread use as it required a lengthy running space which was not present in most Child Development Centres and therefore is not considered feasible for a larger scale study, preventing administration. Furthermore, it must be noted that BOT2 is primarily used in a clinical context with children with developmental coordination disorder (DCD) and this was the first attempt to use this tool with ambulatory CP in this region. Unfortunately applying BOT2 in a population that has impaired limb mobility is difficult, as recording of dominant side only is advised. A future study may look at positive change (if any) in the function of the impaired limb. BOT2 reports only dominant limb change. The short form and balance subscale detected change, with variation between groups, but was unfamiliar to PTs, and added to the time taken to complete measurements. Given the recently reported weak ecological validity of the gross motor subtests of the BOT2 for children with DCD, its suitability to detect meaningful change in children with CP may also be restricted [59].

The Goal Attainment Scale was successfully employed and its use is supported by Levac [19] and van Hedel and Aurich [15]. One parent pointed out that of all the tools, GAS enabled the parent and child to engage in a 'body conversation' about those muscular areas of the body that were engaged during specific activity. This type of conversation during encounters with patients, opens up points of entry about the relationship between body structures and functions [60], and can subsequently assist in fostering a therapeutic environment where capacity for activity and participation increases [61].

SDQ was successfully used and revealed variation in children's social and emotional behaviours e.g. hyperactivity, pro-sociability, conduct, across both groups so

could be employed in a larger trial. As a result of the feasibility RCT, therapists were so impressed with GAS that it was adopted in the local community NHS trust. However, the GAS is less helpful as a measure of group changes, unless weighted functions are incorporated [62] as it is designed to show change for each child individually against that child's personally set goals, which are different for each child. This may be appropriate in 'real life' settings, but will not enable group change to be captured in a trial setting. The Edinburgh handedness inventory was useful when parents and children were unsure of the child's dominant hand, particularly when there was bilateral upper limb involvement.

Limitations/Future adaptations

Treatment fidelity appears to be acceptable however the novelty of the game-based therapy appeared to have worn off by the 7th week. It is essential to find methods to maintain adherence to 12 weeks until more is known about the optimum treatment duration.

Physiotherapists suggested that too many measurements were used during the trial, with some children finding 1.5 to 2 hours of assessment a challenge, especially younger children or children with co-morbidity. The exclusion of BOT-2 may reduce the time of the measurements to under an hour. Physiotherapists may also have found the protocol for phone calls challenging as only half of calls resulted in a conversation. Fewer phone calls but pre-planned timings may be a way forward in future trials.

In a future trial, measurement tools should be streamlined including GMFM as the main outcome, with the addition of the GMFM challenge outcome module [63] to overcome concerns of ceiling effect. GAS and Edinburgh Handedness inventory would also be effective in capturing variation in the therapeutic conversation as well as offer clarity over children's laterality. A future study would also benefit from the employment of a

full-time research therapist to avoid management of clinical caseloads interfering with assessment and data gathering self-direction. Further, dedicated research PTs who have received training in delivering programme advice for SG would also have periodic inter-trainer reliability checks. Equipment would also need to be standardised across clinical environments as is in reality this was often lacking uniformity, relying on therapists to make notes on e.g. height of chairs, use of orthotics.

Adjuncts to therapy

Virtual reality therapy requires the use of therapists or appropriate professionals to steer the direction of activity [15, 19, 28, 64]. VR therapy use therefore does not suggest total automation of therapeutic choices, thereby replacing human and clinical input.

Full Trial

A full trial appears feasible with adaptations to the intervention, such as reduced duration or use of other published material to estimate a minimum sample size. The pooled standard deviation of GMFM-66 at baseline is approximately 12. To detect a 5 point difference between supported and unsupported groups, the effect size (Cohen's D) would be 5/12 =0.41 (i.e. medium). For 80% power at 5% significance, requires 94 children in each group for the analysis are required. Allowing for attrition of 30% (by week 6), 94/0.7 = 134 children would need to be recruited to each group. It is also possible that a focus on 6 to 12 year olds may reduce attrition by 30%, as most drop outs were in children below 6 or over 12 years of age.

Efficiency of analysis can be increased using analysis of covariance (ANCOVA). Assuming a correlation of 0.5 between baseline and follow-up GMFM, the required sample size becomes 71 in each group for the analysis and would require 102

children to be recruited per group accounting for attrition. This currently represents a total sample size of 204.

Conclusion

This study is the first to use an in-home therapy adjunct alongside low cost commercial consoles, with a physiotherapist developed package, with the direct purpose of evaluating participant retention, recruitment and measures. To date, ineffectiveness and lack of standardisation over measures, sample sizes, bespoke versus low-cost console, lack of consistency and clarity over dosage and frequency has meant inadequate outcomes in previous studies. Adding cost-effectiveness –a new element for a feasibility trial - enables health providers to determine the impact and potential utility of this approach, and subsequently impact on NICE (National Institute of Health and Care Excellence) guidelines for care of children with Cerebral Palsy.

There is insufficient evidence to comment on the success of VR therapy, although trends seen in this study mirror most previous studies suggesting improvement in motor function. Therapeutic use of Nintendo Wii Fit™ in-home was inexpensive and acceptable in short periods of around six weeks. Further research is required to compare effectiveness with standard physiotherapy. Positive change to motor outcomes as a result of VR therapy will only be confirmed by larger, sufficiently powered, study. A future trial will be feasible with appropriate modifications to measurement tools, focusing on GMFM as the primary outcome.

Funding acknowledgement and disclaimer

This project was funded by the National Institute for Health Research (NIHR) Research for Patient Benefit Programme number: RfPB PB-PG-0613-31046). The views expressed are those of the authors and not necessarily those of the NIHR, or the Department of Health and Social Care.

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Figure 1 *Process of Informed Consent*

Figure 2 *CONSORT Flow Diagram of Enrolment to Analysis*

Table 1 GRIPP2 Short form of PPI within this trial

Section and topic	**Item**	**Reported on page No**
1: Aim	Report the aim of PPI in the study	11
2: Methods	Provide a clear description of the methods used for PPI in the study	11
3: Study results	Outcomes—Report the results of PPI in the study, including both positive and negative outcomes	19
4: Discussion and conclusions	Outcomes—Comment on the extent to which PPI influenced the study overall. Describe positive and negative effects	20
5: Reflections/critical perspective	Comment critically on the study, reflecting on the things that went well and those that did not, so others can learn from this experience	20

Table 2 Minimisation Balance

	Supported		Unsupported	
	n = 15	%	n = 15	%
Female vs. Male	3	20	5	33
Secondary vs. Primary School Age	4	27	4	27
Bilateral vs. unilateral CP	5	33	5	33

Table 3 Characteristics of Participants

	Supported		Unsupported	
	n = 15	%	n=14*	%
GMFCS 2 vs. 1	6	40	3	21
Left side dominant	7	47	5	43
Right side dominant	6	53	4	57
Neither side dominant	2	13	5	36
Left side affected	8	53	8	57
Right side affected	7	47	6	43

* data missing for one child

Table 4 Percentage of participants using project versus own console

	Supported group		Unsupported group	
	n	%	n	%
Used project console	8	57	12	75
Used own console	6	43	4	25

Table 5 Adherence to Intervention Schedule

	Supported group					Unsupported group					Difference	Bootstrap 95% C.I.* for difference in means
	n	mean	s.d.	median	IQR	n	mean	s.d.	median	IQR	in means	
Number of sessions	11	19	14.6	19	5 to 35	11	24	13.3	30	8 to 36	5	-7.1 to 15.4
Average rating	10	2.4	2	2.1	0.5 to 4.3	8	2.5	1.3	2.6	1.7 to 3.6	0.1	-1.7 to 1.4
Total minutes spent	10	819	634	633	333 to 1065	13	1230	1003	1148	324 to 1547	411	-196 to 1135

C.I.* bias-corrected and accelerated confidence interval

Table 6 Adherence to Intervention Schedule by GMFCS 1 and 2

	GMFCS 1					GMFCS 2				
	n	mean	s.d.	median	IQR	n	mean	s.d.	median	IQR
Number of sessions	16	19.2	13.8	20	6 to 33	6	27.7	13.3	34.5	24 to 35
Average rating	13	2.1	1.6	2.5	0.6 to 3.4	5	3.1	1.9	4	2.3 to 4.3

Table 7 Results for Gross Motor Function Measurement 66, Timed up and Go test, Goal Attainment Scale, Strengths and Difficulties Questionnaire

Outcome measure		Supported group					Unsupported group					Difference	Bootstrap 95% C.I.* for difference in means
		n	mean	s.d.	median	IQR	n	mean	s.d.	median	IQR	in means	
Gross Motor Function Measurement-66	baseline	15	75.2	11.1	72.6	68.9 to 79.1	15	81.4	13.1	84	69.6 to 89.7	-6.2	-14.4 to 3.3
	6 weeks	12	79.2	8.5	79.1	71.6 to 85.3	11	82.8	10.4	88	69.2 to 89.7	-3.6	-10.8 to 4.4
	12 weeks	10	81.7	8.4	82.5	73.1 to 88	11	84.8	10.1	83	71.7 to 92.1	-3	-10.6 to 4.5
Timed Up and Go test (in seconds)	baseline	15	6.2	1.6	5.7	4.8 to 8.0	14	6.6	1.8	6.4	5.9 to 6.9	-0.4	-1.8 to 0.7
	6 weeks	12	5.7	1.5	5.5	4.4 to 6.8	11	6.3	1.8	6.2	4.8 to 8.2	-0.6	-1.8 to 0.8
	12 weeks	10	5.5	1.5	5.3	4.1 to 6.5	11	5.7	1.8	5.3	4.3 to 6.0	-0.2	-1.6 to 1.2
Goal attainment scale	baseline	14	35.2	3.6	36.4	33.3 to 37.1	15	37.6	11.7	33.3	31.2 to 36.6	-2.4	-10.8 to 2.6
	12 weeks	10	54.9	15.5	55	40.3 to 63.9	11	58.8	7.1	56.7	52.7 to 63.5	-3.9	-13.8 to 7.5
Strengths and Difficulties Questionnaire	baseline	15	12.5	6.8	11	8 to 18	15	12.6	6.7	10	8 to 18	-0.1	-5.3 to 4.6
	6 weeks	13	9.5	7.4	9	4 to 14	11	9.8	3.5	10	7 to 12	-1.3	-3.0 to 0.3
	12 weeks	10	10.9	6.8	13	5 to 14	11	9.4	3.4	10	7 to 11	0.1	-1.2 to 1.3

C.I.* bias-corrected and accelerated confidence interval

Table 8 GMFM-66 results by GMFCS

Gross Motor Function Measurement-66 subgroups		Supported group n	mean	s.d.	median	IQR	Unsupported group n	mean	s.d.	median	IQR
GMFCS = 1	baseline	9	80.2	11.5	78.3	72.6 to 81.9	11	85.3	11.3	86.5	74.2 to 96
	6 weeks	7	83.6	8.1	84	79.1 to 86.5	8	86.6	8.1	89.7	84.5 to 89.7
	12 weeks	6	86.2	6.6	86.6	80.9 to 89.7	8	88.3	9	90.9	82.5 to 94.1
GMFCS = 2	baseline	6	67.8	4.6	69.7	64.6 to 70.4	3	73.3	15.3	76.8	56.6 to 86.5
	6 weeks	5	73	3.8	73.1	70 to 73.1	3	72.7	9.9	68.9	65.3 to 84
	12 weeks	4	75	6.1	72.9	71.5 to 78.6	3	75.3	6.7	71.7	71.2 to 83

Table 9 Results for Bruininks-Oseretsky Test of Motor Proficiency

Bruininks-Oseretsky Test		Dominant side										
		Supported group					Unsupported group				Difference	Bootstrap 95% C.I.* for difference in means
		n	mean	s.d.	median	IQR	n	mean	s.d.	median	IQR	in means	
BOT-2 short form	baseline	15	46.5	16.9	48	37 to 62	14	45.8	14.7	42.5	38 to 59	0.7	-12.3 to 10.8
	6 weeks	12	52.2	16.3	57.5	42.5 to 57.5	11	47.4	15.6	50	37 to 65	4.8	-7.7 to 16.7
	12 weeks	10	52.3	15.2	56	43 to 57	11	47.7	15.0	52	37 to 62	4.6	-9.2 to 16.1
Balance	baseline	15	19.9	9.6	17	14 to 29	14	22.4	9.3	25	16 to 29	-2.5	-8.6 to 4.9
	6 weeks	12	22.1	9.9	20	13 to 32	11	25.3	6.6	26	21 to 32	-3.2	-9.1 to 3.8
	12 weeks	10	24.1	10.1	26.5	19 to 32	11	25.1	8.3	29	22 to 31	-1	-8.4 to 6.9

C.I.* bias-corrected and accelerated confidence interval

Figure 1 Process of Informed Consent

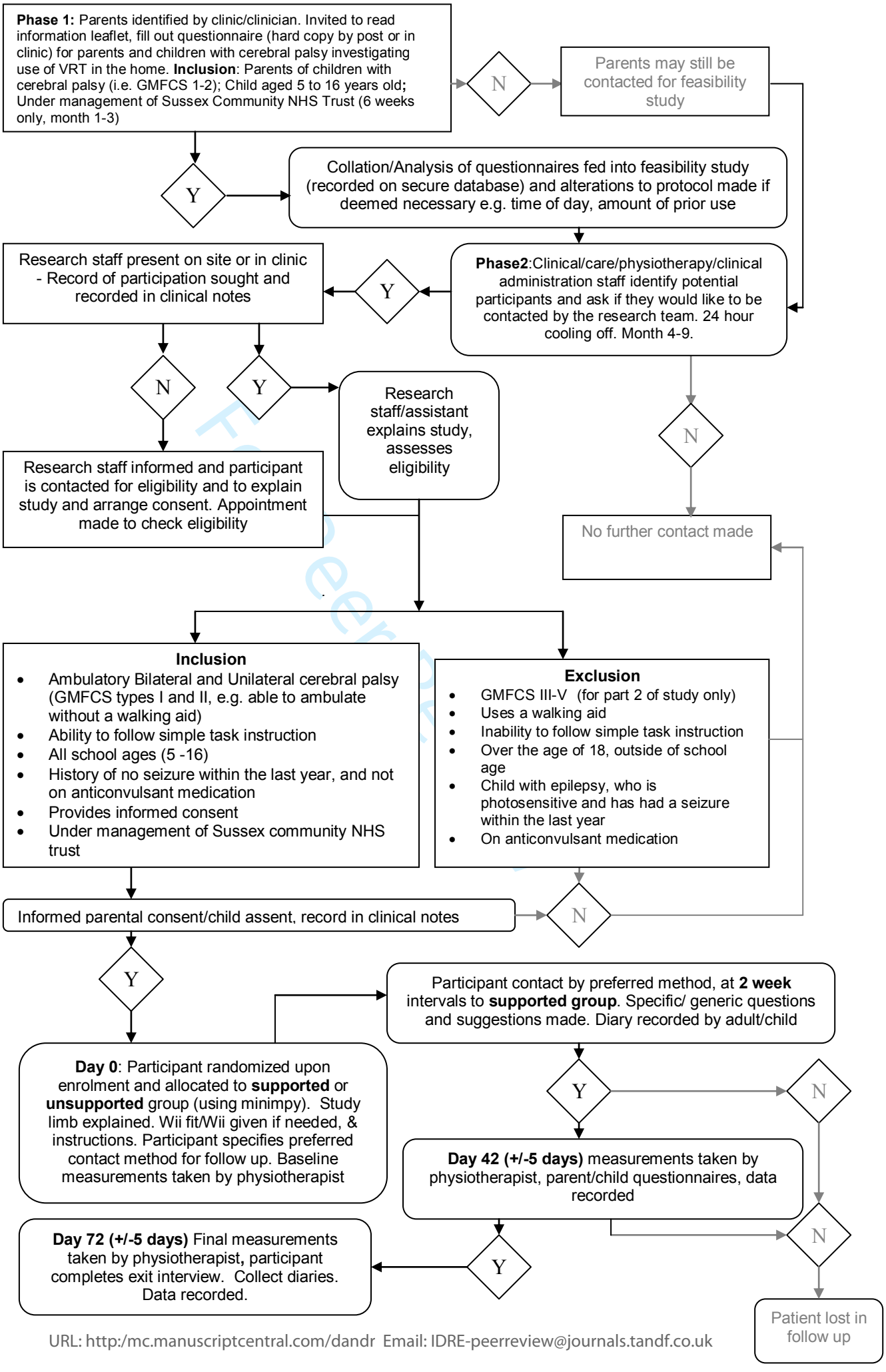
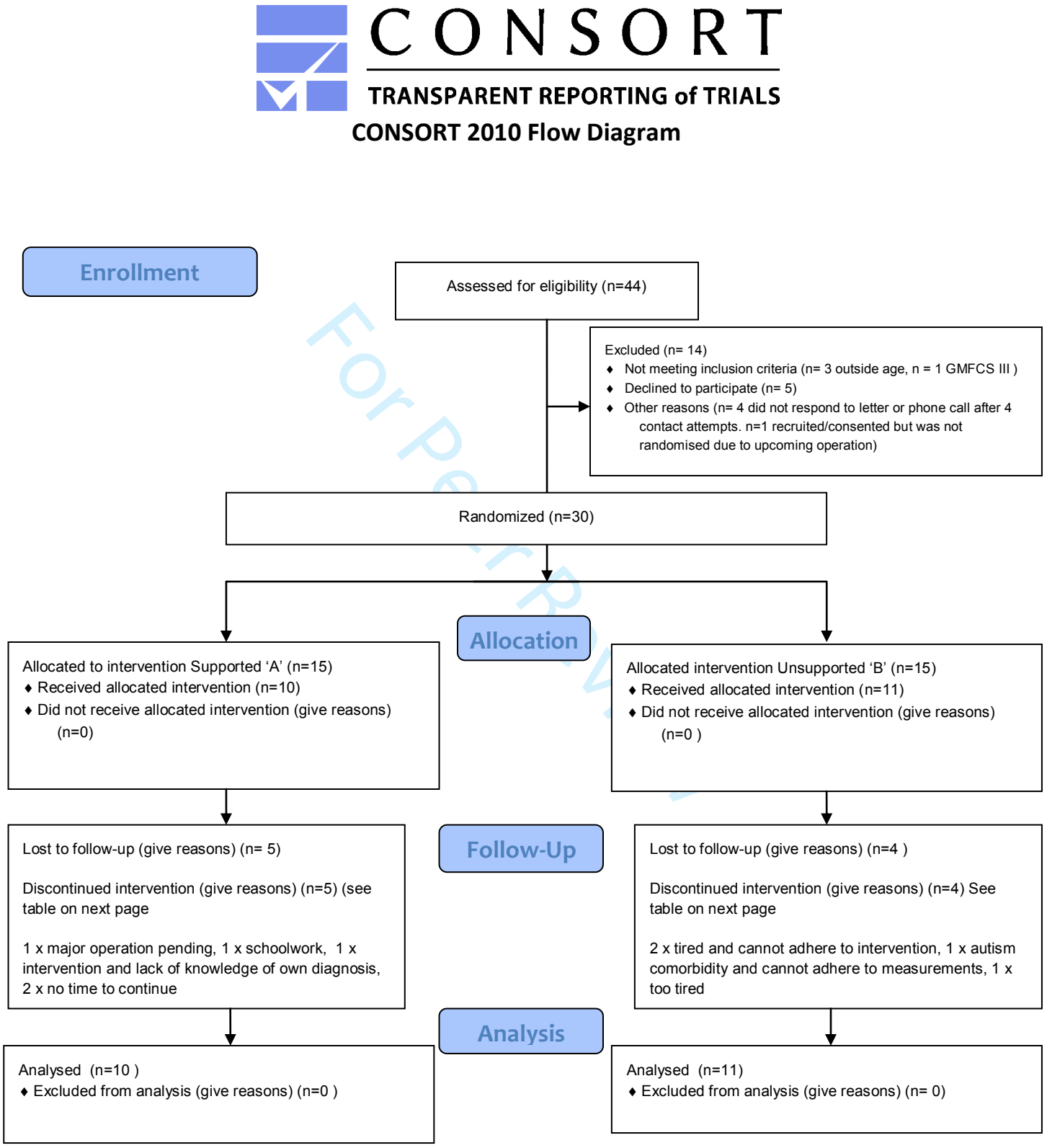


Figure 2 CONSORT Flow Diagram of Enrolment to Analysis



CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	2-5
	2b	Specific objectives or research questions for pilot trial	5
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	1, 8
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	6
	4c	How participants were identified and consented	6-7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	appendix
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	8-10
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	n/a
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	n/a
Sample size	7a	Rationale for numbers in the pilot trial	6
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	8
	11b	If relevant, description of the similarity of interventions	7-10
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	12/13
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Figure 2 (14)
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 2 (14)
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6, 12
	14b	Why the pilot trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 2, 3
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Figure 2 (14)
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	Table 7, 8, 9
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
	19a	If relevant, other important unintended consequences	n/a
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	25-26
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	24, 27
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	20-26
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	24-27
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	1
Protocol	24	Where the pilot trial protocol can be accessed, if available	n/a
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	27
	26	Ethical approval or approval by research review committee, confirmed with reference number	6

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Supplementary Table S1

Participant diary

Can we use the Wii Fit to Help Improve Balance and Movement in Children with CP?

Patient Identification Number for this trial: **Week No:____**

Please complete this diary during your three sessions every week throughout the study. Please be honest. Do not worry if you have missed sessions, as one of the things we want to find out is how well children keep going for a block of virtual reality therapy. Please tell us if you had problems such as the Wii Fit not working, or missed a session, say because you were ill. Please tick the face that shows how much you enjoyed the session using the happy faces scale. Please also use the extra column to record if you have played any extra sessions this week.

	Session one	Session Two	Session Three	Extra Session
Child and/or Carers: How long did you/your child play for?				
Child and/or Carers: Which games did you/your child play on?				
Parents: Was it stressful or was your child happy to do therapy session?	Stressful OK Happy	Stressful OK Happy	Stressful OK Happy	
Child and/or Carers: Any problems/reasons for not doing session?				
Child: How much did you enjoy session?				

Supplementary table S2

Unsupported group had the freedom to choose from the 15 games that were present in the "Wii Fit Sports" game pack training pack. Six games for the supported group were selected from this set of games

Intervention Strategy (supported group) – based on physiotherapist recommended games that focus on particular muscle groups and movement

Please note that it is important to stick to the following schedule and not allow your child to use any other games on the Wii Fit during their intervention sessions -

Remember every week consists of using the Wii Fit 3 times per week, for 30 minutes per session, and keep a record of how you're doing e.g. what levels are you on, or how fast are you getting?

Week	Game & Duration of play for that session	Believed physiotherapy benefit
1.	Penguin Tilt (15 minutes) Followed by Tilt Table (15 minutes)	Introductory session. Penguin Tilt: Good for all ages, core stability, side-to-side weight transfer. Tilt table: Core stability, side-to-side weight transfer, co-ordination
2	Ski Slalom (15 minutes) Followed by Football (15 minutes)	Maintaining previous weeks work on core stability and side-to-side weight transfer. Football: Side-to-side weight transfer,

		balance
3	Snowboard (15 minutes) Followed by Penguin Tilt (15 minutes)	This week whilst still fresh at the start of the session repeat snowboard which you may find challenging, and follow this up with Penguin Tilt from week 1
4	Free choice of the following games: Penguin tilt, Tilt table, Ski Slalom, Snowboard, Football, Balance Bubble. Each chosen game must be played for a minimum of 10 minutes.	This week you can choose any of the games you've been introduced to as a reward as you're halfway through the programme!
5	Ski Slalom (15 minutes) Followed by Tilt Table (15 minutes)	Ski Slalom: Core and quadriceps stability and strength, side-to-side weight transfer Tilt table: Core stability, side-to-side weight transfer, co-ordination
6	Balance Bubble (15 minutes) Followed by Tilt Table (15 minutes)	Balance Bubble: Side-to-side weight transfer, Core and quadriceps stability and strength Tilt table: Core stability, side-to-side weight transfer, co-ordination
7	Football (15 minutes) Followed by	Football: Side-to-side weight transfer, balance

	Snowboard (15 minutes)	Snowboard: Core and quadriceps stability and strength, forward and back weight transfer
8	Free choice of the following games: Penguin tilt, Tilt table, Ski Slalom, Snowboard, Football, Balance Bubble. Each chosen game must be played for a minimum of 10 minutes.	This week you can choose any of the games you've been introduced to as a reward as you're halfway through the programme!
9	Football (15 minutes) Followed by Balance Bubble (15 minutes)	Football: Side-to-side weight transfer, balance Balance Bubble: Side-to-side weight transfer, Core and quadriceps stability and strength
10	Penguin Tilt (15 minutes) Followed by Balance Bubble (15 minutes)	Penguin Tilt: Good for all ages, core stability, side-to-side weight transfer Balance Bubble: Side-to-side weight transfer, Core and quadriceps stability and strength
11	Snowboard (15 minutes) Followed by Ski Slalom (15 minutes)	Snowboard: Core and quadriceps stability and strength, forward and back weight transfer Ski Slalom: Core and quadriceps

		stability and strength, side-to-side weight transfer
12	Free choice of all games -	This week you can choose any game from the Wii Fit including ones you've not played before as you've finished the programme.

Supplementary file S3: Specific Phone Call Question for Participants (every 2 weeks)

1. Did your child require any additional support whilst playing games e.g. holding someone's hand, having a chair in immediately in front of where you are playing?

2. Has your child needed additional support reading what is on the screen e.g. your child can follow instructions verbally but not on the screen?

3. Did your child need support during the 30-minute session i.e. not at the beginning or at the end of the session such as "what do I do now"?

4. How are doing with the games?

5. Do you think you are getting better with the games?

6. What level or times are you achieving?

Specific Phone Call Question For non-supported group (every 2 weeks)

How is it going?